REMARKS

Reconsideration of this application is respectfully requested. Petition is hereby made for a four-month extension of time to respond to the outstanding Final Office Action mailed August 15, 2007. In addition, a Request for Continued Examination is being filed with this Amendment.

Claims 1, 17-19, 56, 58-60 and 83-153 are pending in the application. Upon entry of this Amendment After Final Rejection, independent claims 1, 56, 83, 87, 91, 95, 99, 103, 107 to clarify the invention, dependent claim 134 will be amended to correct the spelling of the word "Shore", new independent claim 154 will be added, and the application specification will be amended, again, to correct the spelling of the word "Shore".

In the outstanding Final Office Action, the Examiner rejected claims 1, 17-19, 56, 58-60 and 83-153 under 35 U.S.C. §103(a) as being unpatentable over U.S. Pub. No. 2002/0091395 of Gabbay ("Gabbay") in view of U.S. Pub. No. 2002/0099438 of Furst ("Furst"). The Examiner's rejection is respectfully traversed.

In rejecting a claimed invention under 35 U.S.C. §103(a) as being obviousness over a combination of references, it remains necessary to identify a reason as to why a person of ordinary skill in the art would have combined the references applied by the Examiner to produce the claimed invention. In rejecting claims 1, 17-19, 56, 58-60 and 83-153 under §103(a), the Examiner simply argues that "[i]t would have been obvious to one of ordinary skill in the art to provide a coating on the elongate structure, as taught by Furst, to Jakobsson

[sic, Gabbay] in order to reduce inflammation, infection, irritation, and/or rejection of the device." 8/15/07 Office Action, p. 3.

Applicant asserts, however, that one of ordinary skill in the art would not have looked to combine Gabbay and Furst, as argued by the Examiner.

Moreover, even assuming, *arguendo,* that the Examiner properly combined Gabbay and Furst in his §103 rejection, Applicant also asserts that the result of this combination would still not be the claimed invention because such references do not disclose an implantable constriction device for forming a restricted stoma opening in the stomach or esophagus of a patient, which is comprised of elongate means or an elongate band for externally constricting the stomach or esophagus of a patient and means for making the constricting means self-supporting that surrounds the constricting means, as now recited in amended independent claims 1, 56, 83, 87, 91, 95, 99, 103 and 107 of the present application.

Turning first to the noted deficiencies in the teachings of Gabbay and Furst, Gabbay purports to disclose a system to help a patient to reduce his or her consumption of food. The system includes a banding apparatus that is applied to around part of the patient's stomach to reduce its diameter and a wrapping apparatus that extends from the banding apparatus and around an upper pouch of the stomach to inhibit expansion of the upper pouch beyond a predetermined volume. The problem solved by Gabbay is the tendency of conventional gastric bands to dislocate and travel downwards towards the lower part of the stomach. See Gabbay, page 1, paragraph [0005].

In his rejection of claims 1, 17-19, 56, 58-60 and 83-153 under §103(a), the examiner alleges that Gabbay discloses an adjustable implantable constriction device for forming a restricted stoma opening in the stomach or esophagus of a patient, comprising an elongate non-inflatable composite structure, which the Examiner identifies as structure 80, 10, or elongate means adapted to externally constrict the stomach or esophagus of a patient, citing also Figures 10 and 11 of Gabbay. 8/15/07 Office Action, page 2. However, the structure 10 of Gabbay cited by the Examiner is a wrapping apparatus, and not a banding apparatus. *See* Gabbay, pages 2-3, paragraphs [0030]-[0036]. This is further clarified in paragraphs 0055-0060 of Gabbay, wherein the function of a wrapping system 190, together with a banding apparatus 144 is described.

The Examiner further identifies Gabbay's implantable banding system 230, shown in Figures 12 and 13 described in paragraphs [0061]-[0063] of Gabbay as the claimed "base material making said structure self-supporting, or means for making the constricting means self-supporting, an adjustment means adapted to mechanically adjust the non-inflatable composite structure to either enlarge or restrict the stoma opening." 8/15/07 Final Office Action, pages 2-3. This banding system 230 is applied around part of a stomach 120. A purse string suture 232 is applied circumferentially around and in and out of the banding 230, as shown in Figure 13. The purse string suture 232 allows the diameter of the banding 230 to be reduced. For this purpose, two ends 234 and 236 of the purse string suture 232 movably extend within and ultimately out of a distal end 242 of an elongated conduit 238 located adjacent to the banding 230, as also shown in Figure 13. The diameter of the

banding 230 may be modified by adjusting the length of the sutures 232 extending from the conduit 238. See Gabbay, page 5, paragraphs [0062] and [0063].

However, as can be further seen from Figure 13 of Gabbay, because the purse string suture 232 extends circumferentially around and in and out of the banding 230, it contacts the patient's stomach 120 at multiple points. It is this contact between the relatively narrow purse string suture 232 (*see,* Figure 12 of Gabbay) and the stomach 120 that could possibly result in an erosion and possible puncture of the stomach wall due to the purse string suture 232 restraining dynamic movements of the stomach.

This is the very kind of problem that is solved by the claimed invention of the present application, *see, e.g.,* Application, page 2, lines 10-14, in which:

(1) a base material or the means for making the constricting means self-supporting surrounds the band or the constricting means, and

(2) the property improving means is applied on the base material or the self supporting means surrounding the band or the constricting means,

as now recited in amended independent claims 1, 56, 83, 87, 91, 95, 99, 103 and 107 of the present application.

Gabbay's gastric band 230 would not benefit from the application of a property improving means being applied to the band because the purse string suture 232 extends circumferentially around and in and out of the banding 230, so as to contact the patient's stomach 120 at multiple points, as shown in Figure 13 of Gabbay.

Thus, in summary, Gabbay discloses a conventional gastric band that is adapted to prevent dislocation thereof, but that does not solve the problems solved by the claimed invention of the present application.

Furst does not compensate for the deficiencies in the teachings of Gabbay. Furst purports to disclose an expandable stent for use within a body passageway. *See* Furst, Abstract. A stent is an expandable metal tubular device that is mounted over an angioplasty balloon and deployed at the site of coronary narrowing. The balloon is inflated to expand the stent to physically open and return patency to the body passageway. After the stent is expanded, the balloon is deflated and removed and the stent is permanently disposed to retain the opened body passageway. *See* Furst, page 1, paragraph [0005]. Thus, Furst has nothing to do with an implantable constriction device for forming a restricted stoma opening in the stomach or esophagus of a patient, as claimed in the present application.

Turning next to the combination of Furst with Gabbay, as noted above, Furst purports to disclose an expandable stent for use within a body passageway. The objects of Furst's invention are listed in paragraph [0011] of Furst, namely to provide a stent that has improved procedural success rates and higher viability under fluoroscopy in vivo, retains its longitudinal dimensions from its original pre-expanded configuration to its expanded configuration, minimizes damage to tissue during insertion and expansion of the stent, inhibits or prevents the occurrence of in-stent restenosis, vascular narrowing and/or restenosis long after the stent has been inserted into a body passageway, and is simple and cost effective to manufacture. Furst, pages 2-3, paragraph [0011].

According to Furst, these objects are attained by, among other things, providing a coating compound securing a biological agent. *See* Furst, page 18, claim 1. Paragraph [0029] of Furst states the following:

> As defined herein, the term "biological agent" is defined as any substance, drug or otherwise, that is formulated or designed to prevent, inhibit and/or treat one or more biological problems, such as, but not limited to, viral, fungus and/or bacteria infection; vascular disorders; digestive disorders; reproductive disorders; lymphatic disorders; cancer; implant rejection; pain; nausea; swelling; arthritis; bone disease; organ failure; immunity diseases; cholesterol problems; blood diseases; lung diseases and/or disorders; heart diseases and/or disorders; brain diseases and/or disorders; neuroglial diseases and/or disorders; kidney diseases and/or disorders; ulcers; liver diseases and/or disorders; intestinal diseases and/or disorders; gallbladder diseases and/or disorders; pancreatic diseases and/or disorders; psychological disorders; respiratory disorders; gland disorders; skin diseases; hearing disorders; oral disorders; nasal disorders; eye disorders; fatigue; genetic disorders; burns; scars; trauma; weight disorders; addiction disorders; hair loss; cramps; muscle spasms; tissue repair; and/or the like.

As such, Applicant concludes that the term "biological agent" appears to include vascular active agents and secondary vascular active agents. It is thus clear that the problems solved by Furst are directed to vascular matters and biological problems.

The present invention relates to a constriction device for forming a restricted stoma opening in the stomach or esophagus of a patient. No such application is disclosed in Furst. On the contrary, a main objective of Furst is to keep a blood passageway open. This objective is attained by providing a biological agent inhibiting and/or reducing restenosis, vascular narrowing and/or in-stent restenosis. *See* Furst, page 8, paragraph [0030]. The

present invention has nothing to do with restenosis or vascular narrowing. The present invention is related to restricting an opening. Furst is related to keeping an opening open.

Furst discloses a stent provided with a biocompatible coating. *See* Furst, page 5, paragraph [0017]. The base material of a stent is conventionally a rather rigid material, such as gold, platinum, steel, *etc.* *See* Furst, page 13, paragraph [0060]. The stent is expanded after insertion into the passageway and is never restricted.

Thus, Applicant asserts that because the problems experienced with a stent are remote from the problems experienced with a gastric band, a person of ordinary skill in the art would never look to document concerned with stents to solve a problem with gastric banding. As such, Applicant further asserts that, given the differences discussed above, a person of ordinary skill in the art would not have looked to Furst as relevant prior art when assessing the problems solved by the claimed invention of the present application, and thus, would not have combined Furst with Gabbay in an effort to produce the claimed invention. A Rule 132 Declaration of Dr. Peter Forsell, the named inventor and applicant in this application, is being submitted with this Amendment in support of these assertions (Attachment A).

In view of the foregoing, it is believed that all of the claims remaining in the application, *i.e.*, claims 1, 17-19, 56, 58-60 and 83-154, are now in condition for allowance, which action is earnestly solicited. If any issues remain in this application, the Examiner is urged to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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